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Sexual sterilisation device

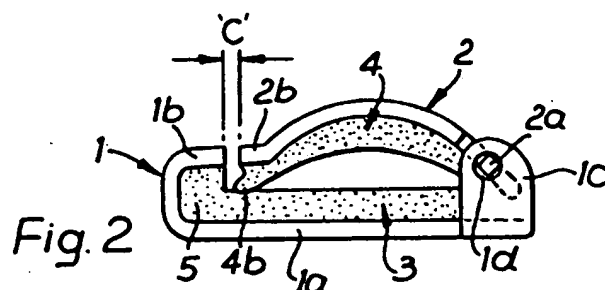
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Applicant: FEMCARE LTD
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Abstract of GB2177748

The device in the form of a clip is designed to prevent, as far as possible failure due to incorrect latching of an upper jaw 2 underneath the lip 1b of a lower jaw by dimensioning the upper and lower jaws such that considerable deformation of the upper jaw is required before correct latching can occur.



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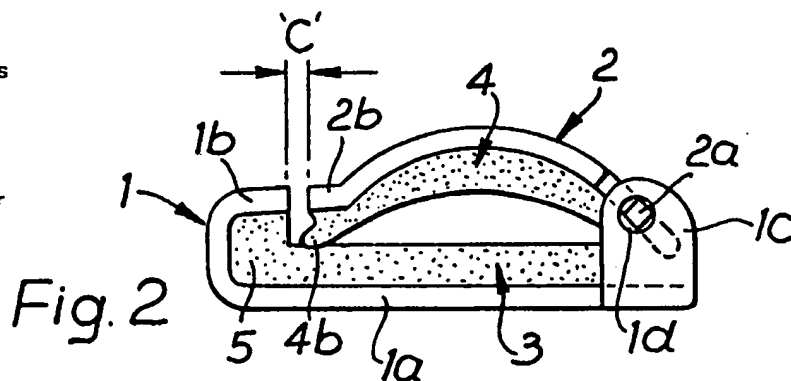
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GB 1530282 GB 1275066 GB 0501059
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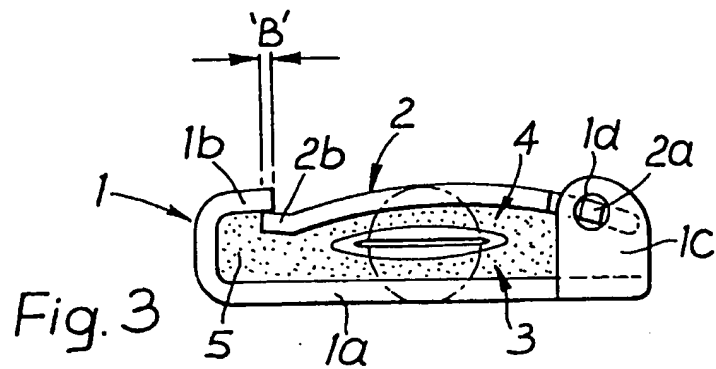
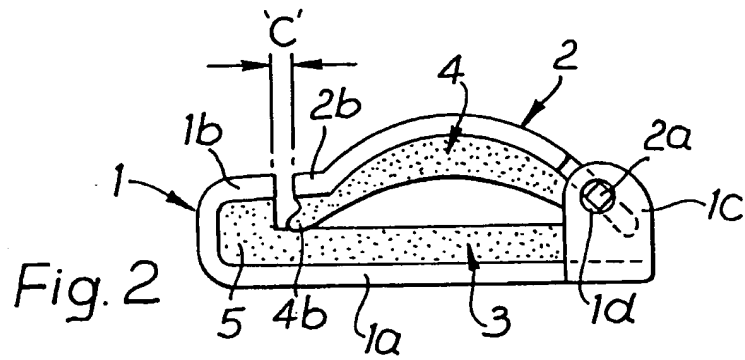
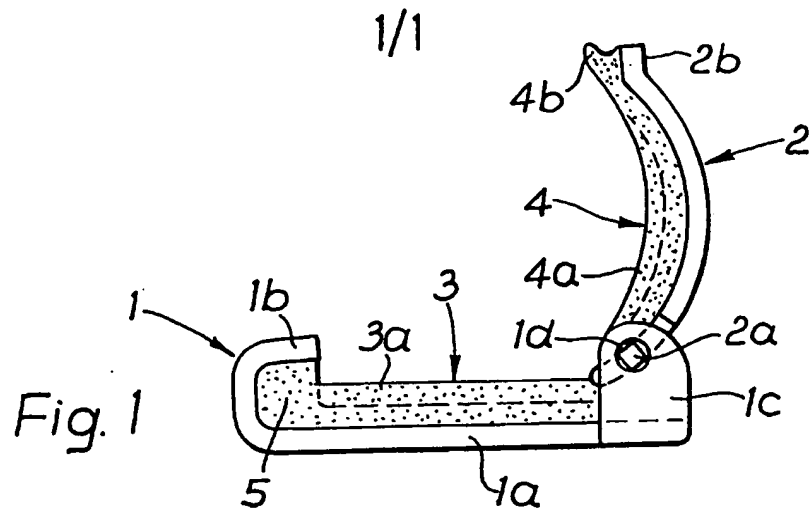
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A44B A61B

(54) Sexual sterilisation device

(57) The device in the form of a clip is designed to prevent, as far as possible failure due to incorrect latching of an upper jaw 2 underneath the lip 1b of a lower jaw by dimensioning the upper and lower jaws such that considerable deformation of the upper jaw is required before correct latching can occur.



GB 2 177 748 A



SPECIFICATION

Sexual sterilisation device

5 This invention relates to a sexual sterilisation device in the form of a clip adapted to be clamped on a Fallopian tube or a vas deferens to effect occlusion thereof.

10 U.K. Patent Specification No. 1 530 282 describes and claims a clip of this general type, and this form of clip has been widely used with a very small failure rate. Improvements in the reliability of this clip have been achieved by providing the clip with a latching arrangement, whereby one jaw is held under a lip on the other jaw, after closure of the clip, but because of the slight inherent resilience of the metal of the clip, titanium, it has been found that it is still possible for a small passageway to be left open for the passage of gametes if sufficient closing force is not exercised on the clip during application, and this could lead to a failure of sterilisation.

25 Additionally, the clips are applied by an applicator which has clamping jaws remotely operated through appropriate linkages. It is possible for the applicator to be incorrectly assembled, for example after disassembly for sterilisation of the instrument, or for the linkages to become worn after prolonged use, in either case making it impossible for the surgeon to apply sufficient pressure to the clip to close it fully. The conventional clip may in these circumstances appear properly closed, but still leave a small passageway for gametes, or the potential for such a passageway after the normal physiological changes in the tube have taken place after clamping.

40 Accordingly, the present invention provides a sexual sterilisation device in the form of a clip adapted to be clamped on and thereby to occlude a duct through which gametes pass, comprising a pair of clamping jaws hinged together, the first jaw having a lip under which the free end of the second jaw is engaged to hold the clip closed, wherein the second jaw is deformable and is dimensioned and arranged such that the free end thereof can only engage under the lip after deformation of the second jaw into occluding engagement with the first jaw.

It will be understood that occluding engagement occurs when the duct is permanently closed to the passage of gametes.

55 Preferably, the second jaw initially curves outwardly between the ends thereof from the first jaw, deformation serving to flatten the second jaw towards the first.

The clip is preferably lined internally with a resilient material, such as a medical grade silicone rubber.

60 It has been found that, using clips according to the present invention, it is impossible to latch the second jaw under the lip of the first jaw and still leave a passage for the gametes,

and it is therefore expected that a significant reduction in the already small number of failures of the clip will be achieved.

70 Reference is made to the drawings, in which:—

Figure 1 is a side elevation of a clip in accordance with a preferred embodiment of the invention, in its fully open position;

75 *Figure 2* is a view corresponding to *Fig. 1*, with the second jaw in position prior to closure of the clip; and

Figure 3 is a view corresponding to *Fig. 1*, with the clip closed on a tube representing a duct for gametes.

80 The clip comprises a first jaw 1 in the form of a flat plate 1a having one end curved over to form a lip 1b, and the other end provided with upstanding side plates 1c with aligned holes 1d therein. A second jaw 2 is formed with small posts 2a extending from each side thereof adjacent to one end, the posts 2a serving as a pivot for mounting in the holes 1d to provide a hinging action between the two jaws. The second jaw 2 is curved so as to present a concave face to the first jaw 1, and has catch portion 2b at the free end thereof, bent outwardly from the concave face.

95 The two jaws 1 and 2 are formed from commercially pure titanium, and are provided with linings 3 and 4 of medical grade silicone rubber. The linings are provided with longitudinal ribs 3a and 4a to reduce the risk of damage to the duct to which the clip is applied. 100 The lining 3 for the first jaw 1 substantially fills the space 5 defined between the lip 1b and the flat part 1a. The lining 4 on the catch portion 2b of the second jaw 2 has a projection 4b.

105 The spacing C (*Fig. 2*) relative to the overall length of the jaw 2 ensures that only when the second jaw 2 is sufficiently deformed to guarantee full occlusion of the tube will sufficient of the catch portion 2b (distance B in *Fig. 3*) be caught under the lip 1b to hold the lip closed. If the second jaw is not sufficiently deformed, and the distance is less than B, the resilience of the projection 4b, coacting with the lining in the space 5, will push the catch portion 2b clear of the lip 1b, and it will be immediately apparent to the surgeon applying the clip that it is not yet latched closed.

115 A further advantage of the resilience of the projection 4b, and the lining in the space 5, is that it prevents excessive deformation of the second jaw 2, with consequent risk of damage to the duct to which it is being applied.

120 In practice, the clip of the invention is applied to a duct by the use of an applicator, which enables the surgeon remotely to locate the clip and then apply pressure to deform the second jaw and close the clip. Such applicators are known for use with existing clips of this type, as hereinbefore described.

130 It will be appreciated that the clip of the

invention can be readily adapted, for example by suitably modifying the dimensions and closure position of the jaws, for use either on the Fallopian tubes or on vas deferens.

5

CLAIMS

1. A sexual sterilisation device in the form of a clip adapted to be clamped on and thereby to occlude a duct through which gametes pass, comprising a pair of clamping jaws hinged together, the first jaw having a lip under which the free end of the second jaw is engaged to hold the clip closed, wherein the second jaw is deformable and is dimensioned and arranged such that the free end thereof can only engage under the lip after deformation of the second jaw into occluding engagement with the first jaw.
2. A sexual sterilisation device as claimed in Claim 1 in which the second jaw initially curves outwardly between the ends thereof from the first jaw, deformation serving to flatten the second jaw towards the first.
3. A sexual sterilisation device as claimed in Claim 1 in which the clip is lined internally with a resilient material.
4. A sexual sterilisation device as claimed in Claim 3 in which the resilient material is medical grade silicon rubber.
5. A sexual sterilisation device as claimed in Claim 3 or Claim 4 in which the resilient material lining the second jaw is shaped to form a projection extending outwardly from the jaw, which projection acts upon the resilient lining on the first jaw to spring urge the jaws apart until the second jaw has been sufficiently flattened to latch the free end securely under the lip of the first jaw.
6. A sexual sterilisation device substantially as described with reference to the accompanying drawings.

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A5R REL

(56) Documents Cited

US 4489725 A US 4485814 A

(58) Field of Search

UK CL (Edition O) A5R REL

INT CL⁶ A61B 17/122 , A61F 6/20 , A61L 17/00 31/00

ONLINE:WPI,CLAIMS

(54) Female sterilisation clip

(57) The clip 1, which is for occluding the Fallopian tube, carries or otherwise incorporates a short- or long-acting local anaesthetic. The latter may be in the form of microcapsules or a gel and may be applied to the inner surfaces 3 of the clip or coated over the entire clip. The surfaces 3 may be impregnated with the anaesthetic or grooves or indentations may be formed in the surfaces of the clip to retain the gel. The clip has an outer layer 2 of titanium lined with silicone rubber, a hinge 4 and a latch 5.

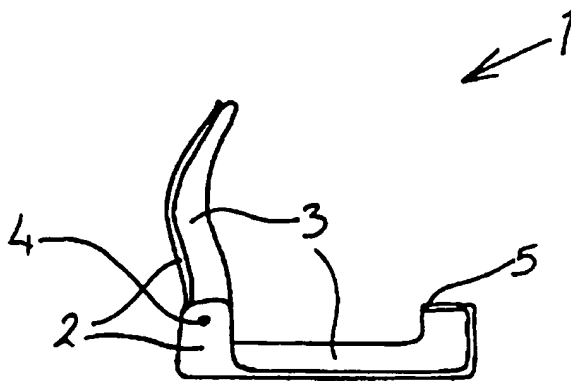


FIGURE 1

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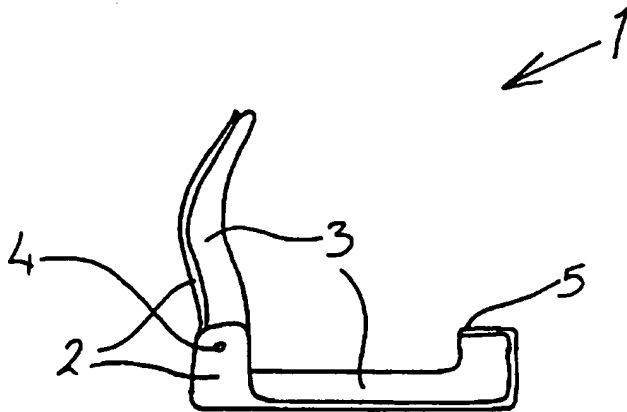


FIGURE 1

STERILIZATION DEVICE

Field of the Invention

This invention relates to a device for female sterilization.

Background to the Invention

5 Tubal sterilization is the world's most popular contraceptive method and is used by many millions of women of reproductive age. It is carried out by laparoscopy or open laparotomy using electrocoagulation or mechanical methods.

10 Increasingly, mechanical methods have replaced electrocoagulation owing to the risk of thermal injury (for example to the bowel or bladder) associated with the latter. Mechanical methods also significantly reduce the risk of subsequent ectopic pregnancies and some other post-operative complications.

15 Clips of various kinds are used in mechanical sterilization methods, for example the Hulka-Clemens clip, the Filshie clip, the Falope ring etc. Their construction and methods of use are well-known in the art and will not be described in detail here.

Female sterilization may be performed under general or local anaesthesia. However, with the increasing desire to reduce the time each patient needs to

5 spend in hospital, the use of local anaesthetic is gaining in popularity. It is already used extensively in the developing world because of its simplicity and safety. The local anaesthetic (for example lignocaine) is injected into the abdomen ensuring that the injection infiltrates all layers of the abdomen down to the peritoneum.

10 One major disadvantage of tubal sterilization using mechanical devices is the increased risk of post-operative pain due to the pressure of the clip on the fallopian tubes. The pain is local to the vicinity of the clip and may last for several weeks. It is thus an object of the present invention to provide a female sterilization clip which reduces the severity of post-operative pain.

Summary of the Invention

15 According to a first aspect of the present invention there is provided a female sterilization clip, carrying or otherwise incorporating a local anaesthetic, the arrangement being such that when the clip is introduced into the patient so as to occlude her fallopian tubes in the correct manner, the anaesthetic has the desired effect.

Preferably, all or part of one or more surfaces of said clip is or are impregnated with said local anaesthetic.

20 In a preferred form, at least one surface of said clip is adapted to receive said local anaesthetic, for example in one or more grooves or indentations. Preferably, said local anaesthetic is in the form of a gel which can be applied to said surface.

25 In a further preferred form, said local anaesthetic is contained within microcapsules which are adapted to enable said local anaesthetic to remain inactive until the fallopian tube is occluded.

Brief Description of the Drawing

Figure 1 shows a schematic view of a Filshie clip.

Description of the Preferred Embodiment

5 One particular type of clip will be used in the following description; this is by no means intended to restrict the application of the invention to such a clip and is given by way of example only.

10 The Filshie clip shown in Figure 1 is made from an outer layer 2 of titanium lined on the inner surfaces 3 with silicone rubber. There is a hinge 4 at one end and a latch 5 at the other. The clip 1 is closed across the fallopian tube (not shown) and latched shut to maintain occlusion.

According to the present invention, the sterilizing clip carries or incorporates a local anaesthetic. The anaesthetic medication may be lignocaine (short-acting), bupivacaine, etidocaine (both long-acting), or any other anaesthetic agent which may be used safely in this area.

15 The anaesthetic may be in the form of a gel which can be applied to at least the inner surfaces 3 of the clip 1 prior to insertion into the patient. The entire clip 1 could be coated in the gel if desired.

One or more grooves, indentations or other recesses in the surfaces of the clip could be used to retain a quantity of anaesthetic gel.

20 Alternatively, the inner surfaces 3 of the clip 1 could be impregnated with the anaesthetic. This eliminates the need for the surgeon to apply anaesthetic gel to the clip; the procedure could thus be simplified by the provision of clip and anaesthetic together in a sterile pack ready for use. This method could be of particular use in developing countries where simple and safe
25 procedures are essential in locations where complex/expensive equipment

and facilities may not be available. Again the entire clip 1 could be impregnated with the anaesthetic if desired.

5 Obviously, the effectiveness of post-operative pain reduction will depend upon the type of anaesthetic used. If a short-acting anaesthetic is used, it may be preferable to contain the active agent in microcapsules for example held in a gel. In this way, the anaesthetic can be released by the action of the surfaces of the clip moving against one another and the fallopian tube, thus providing a controlled release of anaesthetic in the precise location where it is required.

10 Association of a local anaesthetic in this way to a female sterilization clip thus enables the anaesthetic to be applied directly to the vicinity of the clip; this being the main site of post-operative pain. In this way, post-operative pain should be significantly reduced.

CLAIMS

1. A female sterilization clip, carrying or otherwise incorporating a local anaesthetic, the arrangement being such that when the clip is introduced into the patient so as to occlude her fallopian tubes in the correct manner the anaesthetic has the desired effect.
5
2. A female sterilization clip according to Claim 1 wherein all or part of one or more surfaces of said clip is or are impregnated with said local anaesthetic.
3. A female sterilization clip according to Claim 1 or Claim 2 wherein at least one surface of said clip is adapted to receive said local anaesthetic, for example in one or more grooves or indentations.
10
4. A female sterilization clip according to Claim 3 wherein said local anaesthetic is in the form of a gel which can be applied to said surface.
5. A female sterilization clip according to any of the preceding Claims wherein said local anaesthetic is contained within microcapsules which are adapted to enable said local anaesthetic to remain inactive until the fallopian tube is occluded.
15
6. A female sterilization clip substantially as described herein with reference to and as illustrated by the accompanying drawing.
20



The
Patent
Office

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Application No: GB 9501879.2
Claims searched: 1-6

Examiner: L.V.Thomas
Date of search: 18 April 1996

Patents Act 1977
Search Report under Section 17

Databases searched:

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

UK CI (Ed.O): A5R (REL)

Int CI (Ed.6): A61B 17/122; A61F 6/20; A61L 17/00, 31/00

Other: ONLINE : WPI, CLAIMS

Documents considered to be relevant:

Category	Identity of document and relevant passage	Relevant to claims
Y	US 4489725 (Casey et al.) see col.1 ll.22-42	1-4
Y	US 4485814 (Yoon) see col.1 l.67 - col.2 l.27 and col.4 ll.7-17	1-4

X Document indicating lack of novelty or inventive step
Y Document indicating lack of inventive step if combined with one or more other documents of same category.
& Member of the same patent family

A Document indicating technological background and/or state of the art.
P Document published on or after the declared priority date but before the filing date of this invention.
E Patent document published on or after, but with priority date earlier than, the filing date of this application.